K091877 SEP - 2 2009

PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. **Company Name:**
Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142
Chison Medical Imaging Co., Ltd.
No.8, Xiang Nan Road, Shuo Fang, New District, Wuxi, China 214142

Contact: Ms. Ruoli Mo
Tel: +86-510-85311707, 85310593 Fax: +86-510-85310726

U.S. Agent: Bob Leiker
Leiker Regulatory & Quality Consulting
7263 Cronin Circle Dublin, CA 94568
Telephone: 925-556-1302

2. **Device Name:** CHISON Q8/Q6/Q5/Q3 Roll (Portable) Diagnostic Ultrasound System
CHISON iVis 60 & iVis 60 EXPERT (Rollaround) Diagnostic Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II

Classfication Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. **Marketed Device:**
K052042, SonoScape SSI-1000 ultrasound system

3. **Device Description:**
The CHISON Q3/Q5/Q6/Q8/iVis60/iVis60 EXPERT ultrasound system is an integrated preprogrammed color doppler ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The CHISON ultrasound system can be configured either as a portable model (Q3/Q5/Q6/Q8), or as a roll-around model on wheels (iVis60 / iVis60 EXPERT). These systems are designed with the latest technology, using the same quality procedure as ultrasound systems which have been available in the market for years.

This CHISON ultrasound system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound echo data and display the image in B-Mode (including Tissue Harmonic Imaging), M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Power Doppler Mode, Directional Power Doppler Mode, or a combination of these modes.

The CHISON Q Models and iVis60 Models, have been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. **Indications for Use:**
   The system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, tests, thyroid); Heart Soft Tissue; Peripheral Vascular; Musculo-skeletal (conventional) and Urology.

5. **Comparison to Predicate Device:**
   The CHISON Q Models and iVis60 Models are of comparable type and substantially equivalent to the current SSI-1000/SSI-5000 (K052042). All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

6. **Conclusion:**
   The CHISON Q Models and iVis60 systems are substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale and Doppler capabilities. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP - 2 2009

Chison Medical Imaging Co., Ltd.
% Mr. Bob Leiker
Owner and Manager
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

Re: K091877
Trade/Device Name: CHISON iVis 60 & Q Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 17, 2009
Received: June 23, 2009

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CHISON iVis 60 & Q Series Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

D3P64L, 2-4.4MHz Phased Array
D3C60L, 2-5.8MHz Convex Array
D5C20L, 3-8.5MHz Pediatric Micro-convex Array
D6C12L, 4-9.9MHz Transvaginal/Transrectal Micro-convex Array
D7L40L, 4-13MHz Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Mr. Paul J. Hardy at (301) 796-6542.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use

System: CHISON iVis 60 & Q Series Diagnostic Ultrasound Systems
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	Note 1
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1
	Cardiac Pediatric	N	N	N	N	N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes
Note 3: CWD Mode is not available on all transducers.

Additional Comments:

Prescription Use √ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K091877

System: CHISON iVis 60 & Q Series Ultrasound Systems
Transducer: D3P64L, 2-4.4MHz Phased Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1
	Cardiac Pediatric	N	N	N	N	N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes
Note 3: CWD Mode is not available on all transducers.

Additional Comments:

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K091877

System: CHISON iVis 60 & Q Series Ultrasound Systems
Transducer: D3C60L, 2-5.8MHz Convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes
Note 3: CWD Mode is not available on all transducers.

Additional Comments:

Prescription Use √ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091877

System: CHISON iVis 60 & Q Series Ultrasound Systems
Transducer: D5C20L, 3-8.5MHz Pediatric Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N	N	N	N	Note 1
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	Note 1
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1
	Cardiac Pediatric	N	N	N	N	N	N	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes
Note 3: CWD Mode is not available on all transducers.

Additional Comments:

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510(k) Number K091877

System: CHISON iVis 60 & Q Series Ultrasound Systems
Transducer: D6C12L, 4-9.9MHz Transvaginal/Transrectal Micro-convex Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other*. Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	Note 1
	Trans-vaginal	N	N	N		N	N	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)	N	N	N		N	N	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD

Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes

Note 3: CWD Mode is not available on all transducers.

Additional Comments:

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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K091877

System: CHISON iVis 60 & Q Series Ultrasound Systems
Transducer: D7L40L, 4-13MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD Note 3	Color Doppler	Power (Amplitude) Doppler	Other* Combined
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ[1] (Specify)	N	N	N		N	N	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1
	Other (Specify)							

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Note 1: B+M, B+PWD, B+Color Doppler, B+Power Doppler, B+Color Doppler+PWD, B+Power Doppler+PWD
Other*: Tissue Harmonic Imaging, [1] Small Organ: breast, thyroid, testes
Note 3: CWD Mode is not available on all transducers.

Additional Comments:

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510(k) Number K091877